



Arizona Medical Board

9545 East Doubletree Ranch Road • Scottsdale, Arizona 85258

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OFFICE BASED SURGERY STAKEHOLDER'S MEETING

Held at 9:00 a.m. on Monday, September 17, 2007

9535 E. Doubletree Ranch Road • Scottsdale, Arizona

Staff Members

Timothy Miller, J.D., Executive Director

PUBLIC FORUM DISCUSSION

Timothy Miller, J.D., Executive Director opened the meeting at 9:05 a.m. and opened the floor for discussion and suggestions regarding the draft Office Based Surgery Rules ("OBS Rules").

Jeff Mueller, President, Arizona Society of Anesthesiologists (AZSA) spoke about the OBS Rules and stated that he has submitted comments on behalf of AZSA throughout the rulemaking process. Mr. Mueller's comments today are a reiteration of the comments provided on March 5, 2007. AZSA still has two primary areas of concern: The first is the definition of deep sedation. The Rules currently state that a patient may partially lose the ability to lose ventilatory function. Mr. Mueller stated that it is important to state that the patient may completely lose the ability to maintain ventilatory function. To state that a patient partially losing ventilatory function does not provide factual information to the anesthesia provider. Mr. Miller stated the Board would review and reconsider the definition of deep sedation to address this comment. The definition came from the national guidelines. Additionally, the Board does not want to define deep sedation as someone who completely loses ventilatory function because the Board does not want physicians engaging in this type of practice in the office setting. Mr. Mueller said the primary area of concern comes from the word "partially." Mr. Miller stated the Rules require physicians to have the ability to rescue someone from general anesthesia. He asked Mr. Mueller if this is a safeguard for physicians who administer deep sedation. Mr. Mueller said the Rules as currently written do not ensure a safeguard. He stated there should be a specific statement requiring the provider to have a plan to rescue a patient from general anesthesia or a deeper level of anesthesia than planned. This is the core issue in OBS. Many of the adverse outcomes in office settings come from physicians who do not have an appreciation of anesthesia problems. Mr. Mueller suggested inserting language stating that "practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended." Mr. Miller stated that Staff will revisit the correspondence provided by AZSA to see if the issue can be better addressed.

Karen Connell, Mutual Insurance Company of Arizona (MICA) Risk Management Services stated MICA would prefer the term "standards" instead of guidelines in the Notice of Proposed Rulemaking. The use of the term standards in the context of medical care is used to refer to a legal standard of care. Mr. Miller stated he will check with the agency's Rule writer to see what significance the notice of the Rules has to the public and how important the terminology is. The Board does not want to adopt a standard of care because standards evolve over time. The Rules are intended to establish criteria for those aspects of the practice of medicine in OBS that are normally not part of the standard of care. The Rules address things like staffing and equipment. However, there are two aspects of the Rules – patient selection and procedure selection – that touch on the standard of care. Not all procedures that can be done with deep sedation can be done in an office based setting. Mr. Miller will ensure that it is known that these Rules do not set the standard of care. Ms. Connell stated that in a jury trial, this terminology can be used by attorneys as a standard. In the Notice of Proposed Rulemaking, item #8, paragraph two, last sentence, Ms. Connell suggested the language be changed to read "The rules offer non-judicial recourse to a patient who believes a physician who performed OBS using sedation has committed an act of unprofessional conduct because the physician violated the statutes of rules governing office based surgery using sedation."

Additionally, Ms. Connell asked to add a definition for "arterial blood pressure" because failure to define arterial blood pressure could give the impression that invasive intra-arterial monitoring is required. The intent is more likely that the blood pressure may be monitored by sphygmomanometer using manual or automatic means.

Carol Bean, Desert Practice Management stated she has several physician clients that are starting practices where they will be doing office based procedures. Her clients would like a specific definition for conscious sedation. Mr. Miller stated that in the Rules, conscious sedation was divided into three levels of sedation, minimal, moderate and deep. The level of consciousness has always been a key issue. Ms. Bean asked if the Board factored in recovery time of the procedure as it relates to how the level of sedation is defined. Mr. Miller informed her that there can be no overnight or inpatient recovery. The Rules prohibit those types of procedures from being performed in the office based setting. Ms. Bean stated her clients would like examples of procedures that can be done in the office setting. Mr. Miller stated the Board will not provide specific examples, but it will produce and publish interpretive guidelines outlining the Board's view of the rules and why it used certain language. Any procedure using sedation would be covered

under the Rules. The rules will apply if there was a sedative and if the procedure performed is surgical. Arizona statutes currently allow any physician to perform any procedure; however, the procedure must be within the physician's skill set to be within the standard of care. Ms. Bean clarified that an outside anesthesiologist or a CRNA can administer the anesthesia. Mr. Miller confirmed that anyone who has the skills and ability to administer anesthesia may do it. However, it must be within that person's scope of practice. Ms. Bean asked if a medical assistant (MA) can be the primary person in the recovery area. Mr. Miller stated the MA cannot solely staff the recovery area because the healthcare professional must be ACLS and PALS certified. MAs cannot obtain that certification because they are not licensed by the State. The level of person in the room not defined in the Rule other than to state the qualifications for that person. Mr. Miller also clarified that the Rules only apply to the physician performing OBS using sedation. It is not relevant who owns the facility. Physicians should not perform procedures in an environment where the setting is not appropriate. Ms. Bean asked who physicians should contact for interpretation of the Rules. Mr. Miller stated Board staff cannot advise those who we regulate. Physicians should be directed to accreditations who certify particular specialties to see how they define certain procedures. Physicians should also consult with an attorney for specific legal advice. Ms. Bean asked if the Arizona Department of Health Services (ADHS) get involved from a facility point of view. Mr. Miller informed her that the Board has worked closely with ADHS to ensure did not intrude on each other's jurisdiction and ADHS will not be involved.

Tracy Kruse, Independent Accreditation Consultant asked for clarification regarding minimal sedation, specifically, whether it included the use of benzodiazepines. Mr. Miller stated that these types of drugs would fall into the sedation criteria for OBS if they were used to sedate the patient. Ms. Kruse asked if a non-licensed person could monitor the patient in the Perioperative period if there was an ACLS or PALS certified professional on site. Mr. Miller explained that MA could not monitor patients independently, but if the physician or other ACLS or PALS certified personnel are on site and are involved in the overall management of the patient, then the unlicensed staff may monitor the patient. Ms. Kruse asked if the Board considered differentiating the point of discharge from medical discharge. Mr. Miller stated that discharge means physical discharge of the patient from the office. The Board decided that discontinuation of monitoring is a decision that must be made by the physician and is determined by the standard of care.

Chasby Sacks, M.D., Arizona Society of Cosmetic Surgery, stated that many of their members have accreditation from several organizations and asked why the Board did not require accreditation from one of the recognized agencies. Mr. Miller stated there were two reasons for not requiring accreditation: (1) the Rules do not license or regulate the facility, only the physician. Accreditation normally approves office location, etc. The burden is on the physician to determine that the office is safe to perform a procedure. (2) in Arizona, if the facility were licensed, and the procedure cannot be performed in any facility that is not accredited, that would deny the physician an ability to do something without a due process hearing. Arizona requires a dual process system. Additionally, Mr. Miller stated the Board debated whether or not to require physicians performing OBS to have hospital privileges and opted not to require privileges. Currently, minor procedures are performed in doctors' offices without the physician having privileges. The Board is not changing that. If a physician is performing procedures of a deeper sedation or greater complexity he or she may want to consider obtaining privileges for the sake of patient safety.

Ms. Kruse asked if a physician's current accreditation would protect them after these rules go into effect. Mr. Miller stated the physicians practicing in facilities that are accredited would have to meet the requirements of the Rule. Rules apply to the physician at all time. If a physician practices in an accredited facility, he would still need to ensure that the office meets the Rule requirements when he is performing the procedure.

Mr. Miller informed the stakeholders that Staff will review the comments received and at this point Staff can make administrative edits. Any substantive changes will be reviewed with the Board and the Board will determine whether those changes should be made now, in an amendment to the Rule, or not at all. Mr. Miller will e-mail stakeholders with the Board's decision on how to proceed.

The meeting adjourned at 10:10 a.m.

[Seal]



A handwritten signature in black ink, appearing to read "Timothy C. Miller".

Timothy C. Miller, J.D., Executive Director